



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0033]

Morton Grove Pharmaceuticals Inc. et al.; Withdrawal of Approval of Seven Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the *Federal Register* of March 5, 2021. The document announced the withdrawal of approval of seven abbreviated new drug applications (ANDAs) from multiple applicants as of April 5, 2021. The document indicated that FDA was withdrawing approval of the following five ANDAs, after receiving a withdrawal request from Neopharma, Inc., 211 College Road East, Suite 101, Princeton, NJ 08540: ANDA 078383, Pioglitazone Hydrochloride (HCl) Tablets, Equivalent to (EQ) 15 milligrams (mg) base, EQ 30 mg base, and EQ 45 mg base; ANDA 078953, Irinotecan HCl Injection, 40 mg/2 milliliters (mL) (20 mg/mL) and 100 mg/5 mL (20 mg/mL); ANDA 079049, Alendronate Sodium Tablets, EQ 5 mg base, EQ 10 mg base, EQ 35 mg base, and EQ 70 mg base; ANDA 090732, Anastrozole Tablets, 1 mg; and ANDA 203161, Irbesartan Tablets, 75 mg, 150 mg, and 300 mg. Before FDA withdrew the approval of these ANDAs, Neopharma, Inc., informed FDA that it did not want the approval of the ANDAs withdrawn. Because Neopharma, Inc., timely requested that approval of these ANDAs not be withdrawn, the approval of ANDAs 078383, 078953, 079049, 090732, and 203161 is still in effect.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of Friday, March 5, 2021 (86 FR 12950), appearing on page 12950 in FR Doc. 2021-04520, the following corrections are made on pages 12950 and 12951 in the table:

The entries for ANDAs 078383, 078953, 079049, 090732, and 203161 are removed.

Dated: May 14, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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